with the proposed regulation, the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing within 30 days after receiving the proposed regulation, the Administrator may sign the regulation for publication in the Federal Register anytime thereafter. As required by FIFRA section 25(a)(3), a copy of the proposed regulations have been forwarded to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

List of Subjects in Part 170

Environmental protection, Intergovernmental relations, Occupational safety and health, Pesticides and pests, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 136 et seq.

Dated: September 1, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

[FR Doc. 95–23202 Filed 9–19–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 3F4258/P630; FRL–4973–8]

RIN 2070–AC18

Avermectin B_1 and Its Delta-8,9-Isomer; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on the raw agricultural commodity bell peppers. Merck Research Laboratories requested the proposed regulation to establish a maximum permissible level for residues of the insecticide pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: Comments, identified by the document control number [PP 3F4258/P630], must be received on or before October 20, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 3F4258/P630]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: George LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 17, 1993, Merck Research Laboratories, Inc., submitted a pesticide petition (PP 3F4258) requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish a tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on the raw agricultural commodity (RAC) group, fruiting vegetables (tomatoes, peppers, and eggplants) at 0.01 part per million (ppm). On August 9, 1994, Merck requested that the pesticide petition be amended by withdrawing group tolerances and proposing tolerances for bell peppers only at 0.01 ppm., since EPA had concluded there was insufficient data to establish the crop group tolerance and insufficient data to establish a tolerance on all varieties of peppers except for bell peppers.

The data submitted in support of the tolerance and other relevant material have been reviewed. The toxicological and metabolism data and analytical methods for enforcement purposes considered in support of the tolerance are discussed in detail in related documents published in the Federal Registers of May 31, 1989 (54 FR 23209, cottonseed) and August 2, 1989 (54 FR 31836, citrus).

The Agency used a two-generation rat reproduction study with an uncertainty factor of 300 to establish a Reference Dose (RfD). The 300-fold uncertainty factor was utilized for (1) inter- and intra-species differences, (2) the extremely serious nature (pup death) observed in the reproduction study, (3) maternal toxicity (lethality) no-observable-effect level (NOEL) (0.05 mg/kg/day), and (4) cleft palate in the mouse developmental toxicity study with isomer (NOEL = 0.06 mg/kg/day). Thus, based on a NOEL of 0.12 mg/kg/day from the two-generation rat reproduction and an uncertainty factor of 300, the RfD is 0.0004 mg/kg/body weight(bwt)/day.

A chronic dietary exposure/risk assessment has been performed for avermectin B_1 using the above RfD. Available information on anticipated residues and 100% crop treated was incorporated into the analysis to estimate the Anticipated Residue Contribution (ARC). The ARC is generally considered a more realistic estimate than an estimate based on the tolerance level residues. The ARC for established tolerances and the current action is estimated at 0.000022 mg/kg/bwt/day and utilizes 5.4 percent of the RfD for the U.S. population. For nonnursing infants less than 1-year-old (the subgroup population with the highest exposure level) the ARC for established tolerances and the current action is estimated at 0.000072 mg/kg bwt/day and utilizes 17.9% of the RfD. Generally speaking, the Agency has no cause for concern if the anticipated residue contribution for all published and proposed tolerances is less than the RfD.

Because of the developmental effects seen in animal studies, the Agency used the mouse teratology study (with a NOEL of 0.06 mg/kg/day for developmental toxicity for the delta-8,9 isomer) to assess acute dietary exposure and determine a margin of exposure (MOE) for the overall U.S. population

and certain subgroups. Since the toxicological end point pertains to developmental toxicity, the population group of interest for this analysis is women aged 13 and above, the subgroup which most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOEL to the exposure. For this analysis, the Agency calculated the MOE for the high-end exposures for women ages 13 and above. The MOE is 120. Generally speaking, MOEs greater than 100 for developmental toxicity do not raise concerns.

The metabolism of the chemical in plants and animals for the use is adequately understood. Secondary residues occurring in livestock and their byproducts are not expected since there are no known animal feed stock uses for bell peppers. Adequate analytical methodology (HPLC-Fluorescence Methods) is available for enforcement purposes. Prior to publication in the Pesticide Analytical Manual, Vol II, the enforcement methodology is being made available in the interim to anyone who is interested in pesticide enforcement when requested from Calvin Furlow, Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232.

The tolerances established by amending 40 CFR part 180 will be adequate to cover residues in or on bell peppers. There are currently no actions pending against the continued registration of this chemical. Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 3F4258/P630]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP 3F4258/P630] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 28, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation of part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By amending § 180.449 in paragraph (b) in the table therein, by adding and alphabetically inserting an entry for bell pepper, to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million
* * * * *	
Peppers, bell	0.01
* * * * *	

[FR Doc. 95–22869 Filed 9–19–95; 8:45 am]

BILLING CODE 6560–50–F